

§ 178.3280

21 CFR Ch. I (4–1–04 Edition)

List of substances	Limitations
Octadecanoic acid 2-[2-hydroxyethyl] octadecylamino]ethyl ester (CAS Reg. No. 52497–24–2), (octadecylimino) diethylenedistearate (CAS Reg. No. 94945–28–5), and octadecyl bis(hydroxyethyl)amine (CAS Reg. No. 10213–78–2), as the major components of a mixture prepared by reacting ethylene oxide with octadecylamine and further reacting this product with octadecanoic acid, such that the final product has: a maximum acid value of 5 mg KOH/g and total amine value of 86±6 mg KOH/g as determined by a method entitled "Total Amine Value," which is incorporated by reference. Copies of the method are available from the Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.	For use only as an antistatic agent at levels such that the product of film thickness in microns times the weight percent additive does not exceed 16, in polypropylene films complying with § 177.1520(c)1.1 of this chapter, and used for packaging food (except for food containing more than 8 percent alcohol) under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.

[42 FR 14609, Mar. 15, 1977, as amended at 45 FR 56797, Aug. 26, 1980; 45 FR 85727, Dec. 30, 1980; 46 FR 13688, Feb. 24, 1981; 47 FR 26824, June 22, 1982; 51 FR 28932, Aug. 13, 1986; 56 FR 41457, Aug. 21, 1991; 58 FR 57556, Oct. 26, 1993; 60 FR 54430, Oct. 24, 1995; 60 FR 18351, Apr. 11, 1995; 62 FR 31511, June 10, 1997; 63 FR 38748, July 20, 1998; 64 FR 62585, Nov. 17, 1999]

§ 178.3280 **Castor oil, hydrogenated.**

Hydrogenated castor oil may be safely used in the manufacture of articles or components of articles intended for use in contact with food subject to the provisions of this section.

(a) The quantity used shall not exceed the amount reasonably required to accomplish the intended technical effect.

(b) The additive is used as follows:

Use	Limitations
1. As a lubricant for vinyl chloride polymers used in the manufacture of articles or components of articles authorized for food-contact use.	For use only at levels not to exceed 4 pct by weight of vinyl chloride polymers.
2. As a component of cellophane	Complying with § 177.1200 of this chapter.
3. As a component of resinous and polymeric coatings	Complying with § 175.300 of this chapter.
4. As a component of paper and paperboard in contact with aqueous and fatty food.	Complying with § 176.170 of this chapter.
5. As a component of closures with sealing gaskets for food containers.	Complying with § 177.1210 of this chapter.
6. As a component of cross-linked polyester resins	Complying with § 177.2420 of this chapter.
7. As a component of olefin polymers complying with § 177.1520 of this chapter.	For use only at levels not to exceed 2 percent by weight of the polymer.

[42 FR 14609, Mar. 15, 1977, as amended at 55 FR 8914, Mar. 9, 1990]

§ 178.3290 **Chromic chloride complexes.**

Myristo chromic chloride complex and stearato chromic chloride complex may be safely used as release agents in the closure area of packaging containers intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section:

(a) The quantity used shall not exceed that reasonably required to accomplish the intended technical effect

nor exceed 7 micrograms of chromium per square inch of closure area.

(b) The packaging container which has its closure area treated with the release agent shall have a capacity of not less than 120 grams of food per square inch of such treated closure area.

§ 178.3295 **Clarifying agents for polymers.**

Clarifying agents may be safely used in polymers that are articles or components of articles intended for use in

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contact with food, subject to the provisions of this section:

Substances	Limitations
Aluminum, hydroxybis[2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxidato]- (CAS Reg. No. 151841-65-5).	For use only as a clarifying agent at levels not to exceed 0.25 percent by weight of polypropylene and polypropylene copolymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2. The finished polymers contact food only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter or foods only of types III, IV-A, V, VI-A, VI-C, VII-A, and IX as identified in Table 1 of § 176.170(c) of this chapter, under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.
Bis(<i>p</i> -ethylbenzylidene) sorbitol (CAS Reg. No. 79072-96-1) ...	For use only as a clarifying agent at a level not to exceed 0.35 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.2a, or 3.2b, where the copolymers complying with items 3.1a, 3.2a, or 3.2b contain not less than 85 weight percent of polymer units derived from propylene.
Di(<i>p</i> -tolylidene) sorbitol (CAS Reg. No. 54686-97-4)	For use only as a clarifying agent at a level not to exceed 0.32 percent by weight in propylene homopolymer complying with § 177.1520(c) of this chapter, item 1.1, and in olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1 (containing at least 85 weight percent of polymer units derived from propylene), in contact with all food types under conditions of use C through G described in table 2 of § 176.170(c) of this chapter.
Dibenzylidene sorbitol (CAS Reg. No. 32647-67-9) formed by the condensation of two moles of benzaldehyde with one mole of sorbitol, such that the final product has a minimum content of 95 percent dibenzylidene sorbitol.	For use only as a clarifying agent for olefin polymers complying with § 177.1520(c) 1.1, 3.1, and 3.2 of this chapter under conditions of use C, D, E, F, and G, described in table 2 of § 176.170(c) of this chapter at a level not exceeding 0.25 percent by weight of the polymer.
Dimethyldibenzylidene sorbitol (CAS Reg. No. 135861-56-2)	For use only as a clarifying agent at a level not to exceed 0.4 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene. The finished polymers shall be used in contact with food under conditions of use A through H described in table 2 of § 176.170(c) of this chapter.
Polyvinylcyclohexane (CAS Reg. No. 25498-06-0)	For use only as a clarifying agent for polypropylene complying with § 177.1520(c) of this chapter, item 1.1., and in propylene containing copolymers complying with § 177.1520(c) of this chapter, items 3.1 and 3.2, at a level not exceeding 0.1 percent by weight of the polyolefin.
Sodium di(<i>p</i> - <i>tert</i> -butylphenyl)phosphate (CAS Reg. No. 10491-31-3).	For use only as a clarifying agent at a level not exceeding 0.35 parts per hundred of the resin in olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene).

Substances	Limitations
Sodium 2,2'-methylenebis(4,6-di- <i>tert</i> -butylphenyl)phosphate (CAS Reg. No. 85209–91–2).	<p>For use only:</p> <ol style="list-style-type: none"> 1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H, described in table 2 of § 176.170(c), or foods of all types, limited to conditions of use C through H described in table 2 of § 176.170(c). 2. As a clarifying agent at levels not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1(a) or 1.1(b) and of olefin polymers complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b) (where the copolymers contain not less than 85 weight percent of the polymer units derived from polypropylene.) The finished polymers shall be used in contact with foods only under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV-B, VI-A, VI-B, and VII-B as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV-A, V, VI-C, and VII-A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

[46 FR 59236, Dec. 4, 1981, as amended at 52 FR 30920, Aug. 18, 1987; 53 FR 30049, Aug. 10, 1988; 54 FR 12432, Mar. 27, 1989; 54 FR 14734, Apr. 12, 1989; 55 FR 52990, Dec. 26, 1990; 56 FR 1085, Jan. 11, 1991; 59 FR 13650, Mar. 23, 1994; 59 FR 25323, May 16, 1994; 61 FR 33847, July 1, 1996; 61 FR 51588, Oct. 3, 1996; 61 FR 65943, Dec. 16, 1996; 63 FR 56789, Oct. 23, 1998; 63 FR 68392, Dec. 11, 1998; 64 FR 26843, May 18, 1999; 65 FR 16316, Mar. 28, 2000]

§ 178.3297 Colorants for polymers.

The substances listed in paragraph (e) of this section may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions and definitions set forth in this section:

(a) The term *colorant* means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term “colorant” includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Center for Food Safety and Applied Nutrition, (HFS-200) Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.